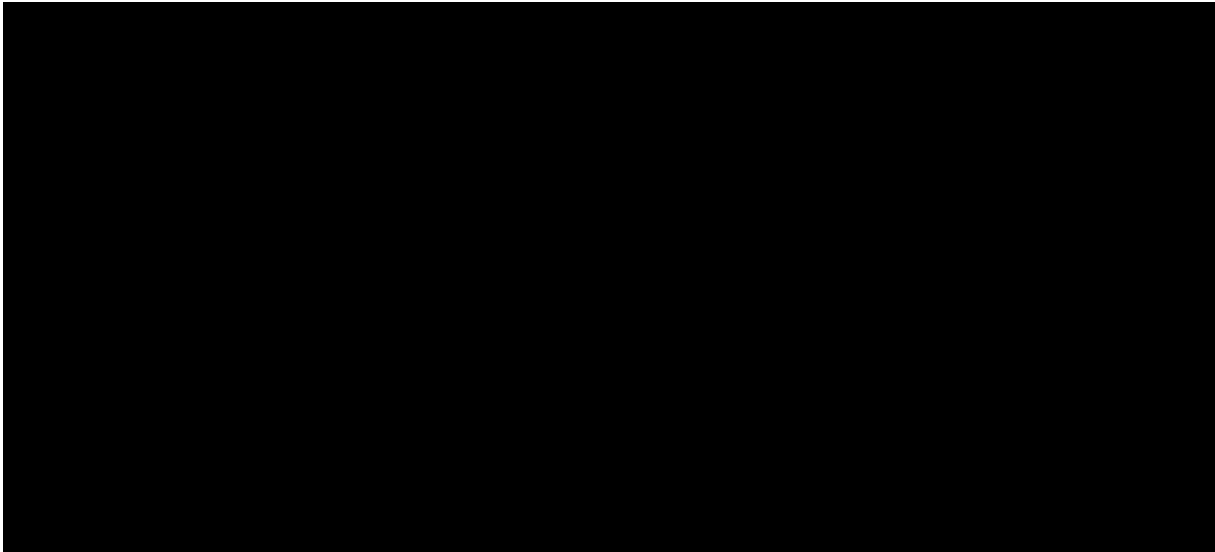|	
From:	Wong, Natalie [/O=BARD/OU=TPE AG/CN=RECIPIENTS/CN=NWONG]
Date:	5/20/2004 5:06:03 PM
To:	Uelmen, Doug [Doug.Uelmen@crbard.com]
Subject:	RE: ██████████████████
Attachments:	████████████

Doug,

I have evaluated the data comparing Recovery with the Other Products. These results include Q2 2004.

Based on the limited amount of data, the following can be concluded.

Please let me know if you have any further questions.

Thanks,

Natalie Wong

NPD Quality Engineer

phone: X-2615

email: natalie.wong@crbard.com

-----Original Message-----
From: Uelmen, Doug
Sent: Tuesday, May 18, 2004 11:54 AM
To: Wong, Natalie
Subject: FW ███████████████████████

Dear Natalie,

The Data.

Doug

-----Original Message-----
From: John Lehmann [mailto:jlehmann@lehmannthomas.com]
Sent: Friday, April 23, 2004 9:05 AM
To: Carr, Robert
Cc: Uelmen, Doug; Ganser, Christopher
Subject: RE ████████████████████

██
██
██

J.

_____

From: Carr, Robert [mailto:Robert.Carr@crbard.com]
Sent: Friday, April 23, 2004 11:51 AM
To: John Lehmann
Cc: Uelmen, Doug
Subject: RE: ███████████████████

Thanks, that looks great. Please let me know if you need anything else.

-Rob

-----Original Message-----
From: John Lehmann [mailto:jlehmann@lehmannthomas.com]
Sent: Friday, April 23, 2004 7:57 AM
To: Carr, Robert; Uelmen, Doug
Cc: Ganser, Christopher
Subject: Draft data set for statistician

Rob, Doug, here's the data set I sent to the statistician this AM. Please let me know if I've interpreted everything correctly.

The numerator event of interest is death due to: 1) migration 2) caval perforation 3) caval obstruction or 4) PE / acute respiratory event. The denominator is IMS estimated sales.

I believe that the under-reporting of nonsignificant migrations will be so extreme that calculating a 'proportion of migrations that are fatal' based on MAUDE data will be entirely suspect. We should stick to the much more likely to be reported event of filter associated death, compared to estimated sales. This also has the best clinical relevance for practitioners.

Everyone who reviews this data must remain cognizant of the many potential flaws of the numbers and of the associated analyses:

1) event data suffers from unknown levels of under-reporting, which can vary substantially between manufacturers (for example, we know of SNF deaths that were not reported by its prior owners

2) sales data is only estimated

3) inventory levels can cause unknown delays between sales and use

4) the event of interest is very infrequent (1 in 10,000 uses generally) (which does indicate how effective these devices are, compared to the likely mortality of PEs in this high risk population)

5) the data is lumpy, with most devices having periods of higher events, followed by periods of no events

So the output from the statistical analysis will not be dispositive, but only give a rough indication of whether we are facing an event rate that is meaningfully and reliably higher than expected, given the kinds of variability evident in this data.

Kind regards, John

cc Chris Ganser